

Chapter 18

Conflict of Interest Requirements

Prisma Health policies and procedures for the disclosure and management of research conflict of interest (COI) are fully delineated in separate Institutional policies and procedures. A summary is provided in this document; however, the Institutional policies and procedures should be consulted directly for definitive information about these requirements.

Conflicts of Interest may be interpreted to include any situation in which financial, professional, or personal obligations may compromise or present the appearance of compromising an individual's or group's professional judgement in conducting, reviewing, or reporting research.

The IRB is also required to evaluate organizational conflict of interest. The process for assessment of institutional conflict occurs on an annual basis. Specifics related to this process and its requirements are detailed in Prisma Health Policy: Financial Conflicts of Interest for the Institution: Research-Prisma Health.

Federal regulations at Title 21 Part 50 and Title 42 Part 50 of the Code of Federal Regulations require the disclosure and management of financial Conflicts of Interest in research. Federal human subject protection regulations at 21 CFR 56.107(e) and 45 CFR 46.107(d) require IRB members to be free of any conflict.

Disclosure Requirements

Investigators and research staff participating in human subject research whether or not employed by Prisma Health must disclose to the Prisma Health compliance office their relevant financials interests as well as those held by their spouse and dependent children.

In addition, each investigator participating in Prisma Health research involving human participants must abide by the COI polices of their primary institution. When applicable, by FDA regulation 21 CFR 54." Financial Disclosure by Clinical Investigators" for investigational drug, biologic, and device studies. In the context, participating in human subject research includes being responsible for the design, conduct, or reporting of research.

Financial Disclosure information must be submitted prior to review of any study by the IRB. Financial Disclosure is submitted through the COI disclosure system managed by the Prisma Health Compliance department. This must be updated annually and within 30 days of any change to changes in financial interest profile.

For detail and more specific information see Prisma Health Policy

Conflict of Interest Annual Disclosure Requirements (S-015-03)

Conflict of Interest Annual Disclosure Appendix A: Definitions

Conflict of Interest Annual Disclosure Appendix B: Specific

Actions Financial Conflict of Interest for Researcher and Research Staff

Financial Conflict of Interest for the Institution – Research -Prisma Health

[found in Policy Tech: <https://prismahealth.policytech.com/>]